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| 09/960,321 | 09/24/2001 | Lloyd L. McCall | N1379-006 | 5340 |

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JONDLE & ASSOCIATES P.C.
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CENTENNIAL, CO 80112

EXAMINER

BUI, PHUONG T

| ART UNIT | PAPER NUMBER |
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1638

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DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,321

Applicant(s)

MCCALL, LLOYD L.

Examiner

Phuong T. Bui

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

1. Claims 1-24 are examined in the instant application.

Specification

2. The abstract of the disclosure is objected to because the word “novel” should be deleted, as novelty has not been established; and if the claimed invention is determined to be patentable, then novelty is presumed. Correction is required. See MPEP § 608.01(b).
3. The disclosure is objected to because of the following: the claims recite ATCC Accession information not disclosed in the specification. Applicant is required to provide the corresponding ATCC Accession information in the specification also. Compliance with this requirement may be held in abeyance until patentability is determined.

On page 19, paragraph [0113], “mosaic” is misspelled.

Drawings

4. No drawing has been submitted in the instant application.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ATCC Accession No. information in claims 1 and 14 are incomplete.

In claim 7, “A” should be amended to “The” for proper antecedence.

In claim 8, it is suggested that “is capable of expressing” be amended to “having”, as no conditions for expressing are set forth to define “capable of”, and “expressing” implies protein expression, which does not appear to be Applicant’s intention.

The recitations of “relative maturity”, “approximately”, “excellent”, “above average general appearance”, “adapted” and “regions” in claims 15, 17, and 22 are unclear because the metes and bounds of these terms cannot be assessed. Furthermore, they lack a comparative basis. Additionally, the metes and bounds of “adapted to ... regions of the United States” are unclear because no specific states or other objective geographic demarcations are set forth for the regions; it is unclear what other states are being encompassed; and the boundaries for these states are not based upon differences in climate or plant growth conditions. Moreover, does Applicant intend to encompass entire states, regions thereof, or only the climatic conditions of these states? How would one be able to ascertain whether or not a plant is adapted for these areas?

The recitation of “derived” in claims 16 and 17 is unclear. Claim 14 indicates how the “SG5611NRR-derived” soybean plant was obtained. Thus, it is clear in claim 14 as to what is being retained in the “derived” soybean plant. However, such is not the case with claims 16 and 17. In claims 16 and 17, it would appear that the “SG5611NRR-derived” plant of claim 14 is not the same as the “SG5611NRR-derived” plant of claims 16 and 17. It is also noted that in claim 16, the derived soybean plants in step (a) differ from those of step (c). Therefore, it is unclear as to what is being retained in the “SG5611NRR-derived” plants of claims 16 and 17.

In claim 18, it is suggested that “derive” be amended to “obtain”, to avoid the ambiguity of deriving from a derived plant.

In claim 22, it would appear that Applicant intends for "5.0 to 6.0" to be the relative maturity. However, such is not stated.

In claim 23, "employing a soybean plant as a source of plant breeding material" is not a plant breeding technique. Further, claim 23 is an incomplete method claim because it does not recite positive method steps for developing a soybean plant. "Using" and "employing" are not clear, positive step recitations. Also, there is no nexus between the breeding techniques recited and the method for developing a soybean plant. How do the breeding techniques result in "developing a soybean plant"?

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, 1st paragraph, enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a reproducible process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that Applicant intends to deposit the claimed seed at

the ATCC, but there is no indication that the seed has been deposited and there is no indication in the specification as to public availability. If the deposit of the seed is made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating the seed will be irrevocably, and without restriction or condition, released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

The deposit information on page 29 of the specification does not fully comply with the deposit requirements because a proper deposit has not been made; and Applicant failed to state that the deposit will be made under the terms of the Budapest Treaty or in compliance with 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

9. Claims 11-13, 15-17 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines. The claims are drawn to soybean progeny plants having undisclosed identifying characteristics whereby only one parent in the first cross is known, and none of the parents in any of the subsequent crosses are known. The claims are also drawn to methods of producing F2 and further descendants of F2. The claims are also drawn to a plant containing transgenes and a method for producing a progeny plant containing transgenes. Applicant should note that no identifying characteristics are set forth even for the F1 progeny. In paragraph 9 of the specification, Applicant states "The cultivars which are developed are unpredictable. This unpredictability is because the breeder's selection occurs in unique environments, with no control at the DNA level (using conventional breeding procedures), and with millions of different possible genetic combinations being generated. A breeder of ordinary skill in the art cannot predict the final resulting lines he develops, except possibly in a very gross and general fashion. The same breeder cannot produce the same cultivar twice by using the exact same

original parents and the same selection techniques.” If the claimed F1 plant itself cannot be identified by characteristics clearly disclosed in the specification, then it is not even possible to determine whether a plant of unknown parentage is or is not covered by the claim. Thus, F1 progeny plants that are not disclosed by any identifying characteristics are not considered to be possessed by Applicant. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation, absent further guidance. The breeding techniques disclosed encompasses conventional cross hybridization using two parent plants that are genetically distinct from each other. Each of these breeding techniques would result in a structurally and phenotypically different plant. Over an undetermined number of generations, the identifying characteristics for each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification or set forth in the claims. Additionally, in the method claims, neither the starting materials nor the end product is adequately described. Applicant should note that methods which generate F1 are adequately described because the F0 parent is adequately described, and crossing an F0 parent with another parent to select for particular traits or characteristics in the F1 progeny plants is routine in the art. However, in methods to generate F2, no traits or characteristics are disclosed for the F1 parent, as indicated above. The disclosure of F1 traits is essential to the claimed invention since the F1 parent is required to generate F2 progeny plants. Thus, these methods would involve crossing two parents having unknown characteristics to generate F2 progeny plants having unknown characteristics. This same unpredictability is applicable to a plant containing transgenes and using conventional breeding to

generate plants containing transgenes. The deposited seed has a defined set of genes and corresponding traits, and it is unpredictable how an unidentified transgene(s) when introduced into a plant would alter the genetic makeup of the deposited seed and affect the genotype and phenotype of the resulting transformed plant. If a transgene is incompatible with another introduced transgene or is incompatible with a gene(s) of the deposited seed, it is unclear what the resulting genetic makeup of the claimed transformed plant is. Accordingly, there is a lack of adequate description for the claimed progeny plants, methods for generating F2 and subsequent progeny plants and plants containing transgenes, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Accordingly, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111).

Claim Rejections - 35 USC § 112, 1st paragraph, enablement

10. Claims 19-21, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for soybean plants grown from the deposited seed (F0) and methods for producing F1 plants whereby one parent plant is the plant from deposited seed, does not reasonably provide enablement for plants and methods of producing plants containing unidentified transgenes, and plants and methods of producing plants by transformation with unidentified genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The breadth of the claims encompasses unidentified or unknown

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transgenes inserted into unidentified locations on the plant genome. Applicant provided no working example of plant transformation with transgenes and their insertion into any region of the plant genome. While transgenes encoding proteins having a particular beneficial effect such as insect resistance are known in the art, it is unclear how one skilled in the art would be able to make and use unidentified or unknown transgenes. It is also unpredictable how the expression of such transgenes would affect the genotype or phenotype of the resulting plant, as random insertion of transgenes may disrupt the expression of other plant genes and may “knock out” beneficial properties or traits present prior to the transformation. Moreover, the expression of the transgene may be “masked by other confounding plant traits or environmental factors” (specification, [007]), thus negating any potential benefit the transgene may have. Due to the complexity of the plant genome and the billions of different genetic combinations possible (specification [008]), it is not known in the art how the transgene would affect the genotypic and phenotypic expression of traits of the transformed resulting plant. Thus, absent further guidance as to what trait the transgene confers and where on the plant genome the transgene should be inserted (site specific transformation), it is unpredictable that the transgene would have any beneficial effect, and that the plant would retain all the desirable traits of the untransformed plant. Accordingly, Applicant has not enabled any transgene for transformation into a plant.

Claim Rejections - 35 USC § 102 and 35 USC § 103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 11-13, 15, 17, 21, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Luzzi (US Pat. No. 5977444 (A)). Luzzi teaches a soybean plant and seed, wherein said plant or seed has white flower color, gray pubescence color, buff hilum color, tan pod color, determinate plant habit, excellent/superior yield, Roundup Ready resistance, adapted to the Midsouth/Southcentral region of the United States (col. 5), plant lodging score of 1.3, and plant height of 33.5 inches (col. 6, Table 1). The plant of Luzzi appears to be of "above average general appearance" (col. 6, Ins. 19 and 28). While the soybean variety of Luzzi is designated 9500029615545 and the parent soybean variety of the instant application is designated SG5611NRR, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. Furthermore, the language used in the claims does not adequately set forth the metes and bounds of the claimed invention (see 112 second paragraph rejections above). Even at the F1 progeny level, no identifying characteristics are recited to distinguish Applicant's F1 plants from those of the prior art. The claims do not specifically recite a plant whereby "all of the physiological and morphological characteristics" of the SG5611NRR parent are retained. The methods used to produce the claimed plants involve an undetermined number of crosses and not all of the distinguishing characteristics of the SG5611NRR parent from the initial cross are necessarily retained. None of the identifying features which distinguish Applicant's plants from

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those of the prior art are set forth (see written description rejection above). The method of producing the plant, namely using soybean SG5611NRR as the first parent during multiple generations and crosses, would not confer a unique property to the resultant soybean which would distinguish it from the prior art soybean, particularly if the claimed breeding method was followed by multiple generations of outcrossing to a non-SG5611NRR parent. Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

13. No claim is allowed.

14. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703)308-4242. All Technology Center 1600 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Bui whose telephone number is (703)305-1996. The Examiner can normally be reached Monday-Friday from 6:30 AM – 4:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703)306-3218.


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Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703)308-0196.

Phuong Bui
Primary Examiner
Art Unit 1638
August 16, 2003


PHUONG T. BUI
PRIMARY EXAMINER 9/1/03